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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PACIRA PHARMACEUTICALS, INC., and PACIRA BIOSCIENCES, INC.,

Plaintiffs,

v.

eVenus PHARMACEUTICALS LABORATORIES, INC., JIANGSU HENGRUI PHARMACEUTICALS CO., LTD., and FRESENIUS KABI USA, LLC,

Defendants.

Civil Action No. 2:21-cv-19829
Civil Action No. 2:22-cv-00718
(consolidated)

Assigned to:
Judge Madeline Cox Arleo
Magistrate Judge José R. Almonte

DEFENDANTS' POST-CLOSING REBUTTAL STATEMENT

Pursuant to the Court's authorization, Defendants provide the following responses to arguments raised by Pacira during its rebuttal at the May 7, 2024 closing arguments.

Inequitable Conduct: Pacira offers piecemeal, after-the-fact excuses for Ms. Los's and Dr. Dai's actions; however, none of these excuses are persuasive in view of all the evidence, and none explain their overall pattern of conduct. *See Luv n' Care, Ltd. v. Laurain*, 98 F.4th 1081, 1098 (Fed. Cir. 2024) ("[I]t is not enough for a court to consider each individual act of misconduct without also considering the collective whole.").[1] Ms. Los and Dr. Dai affirmatively concealed key data from the PTO, then made arguments to the Examiner that were inconsistent with that concealed data in order to obtain the '495 Patent. D.I. 365-1 ("FOF") ¶¶ 437-78, 494-553. The single most reasonable inference in view of the totality of evidence is an intent to deceive the PTO.

Pacira's withheld anticipatory one-month data is not "cumulative" to Figure 3B, which does not disclose the actual, measured one-month data in Dr. Dai's and Ms. Los's possession; at most, it presents an unreliable "extrapolation." *Id.* ¶¶ 338-43. Also, the Los Spreadsheet showed that multiple batches of EXPAREL®

[1] In *Luv n' Care*, which issued on April 12, 2024, the Federal Circuit remanded as the district court had only considered "individual acts of misconduct in isolation and failed to address the collective weight of the evidence regarding each person's misconduct as a whole." 98 F.4th at 1098.

anticipated claims 3 and 5. *Id.* ¶¶ 350-53. This information is not discernable from Figure 3B. Tr. 777:19-778:4 (Klibanov). Moreover, Dr. Dai and Ms. Los did not merely withhold data—they affirmatively concealed it through falsely stating in Table 1A that the data did not exist ("n/a"). FOF ¶¶ 354-59, 463-68, 493-504. Data is not "cumulative" if successfully concealed or misrepresented, even if it was provided to the PTO in some format. *See Luv n' Care*, 98 F.4th at 1098. Pacira's only excuse for the use of "n/a" is that Ms. Los (who did not draft Table 1A) believed it was not possible to accurately report an average for the one-month timepoint, because certain batches had a value of less than 20 µg/mL. This "excuse" concedes that the use of "n/a" in Table 1A was an intentional drafting decision motivated by the anticipatory one-month data. However, it does not explain how "n/a" could be read as anything other than false or misleading, in the absence of the full underlying data, or why Ms. Los and Dr. Dai excluded the full batch data from the '495 Patent.

Similarly, although Pacira now concedes that there is no meaningful difference in stability at the one-, two-, and three-month timepoints (Trial Tr. 32:12-24), that is not what Dr. Dai and Ms. Los told the PTO. Instead, they consistently represented to the PTO that the "new" product had "improved stability" over all claimed timepoints. FOF ¶¶ 17-19, 26-38, 372-80. Moreover, Ms. Los knew that even the claimed six-month values were not novel based on the Ardekani Data, which she understood to reflect the properties of prior art EXPAREL®. *Id.* ¶¶ 505-

521, 531-32. Pacira's withheld data was "directly at odds with its argument[s] during prosecution" to obtain the '495 Patent, and was therefore but-for material. *Belcher Pharms., LLC v. Hospira*, 11 F.4th 1345, 1353 (Fed. Cir. 2013).

Pacira speculates that in certain subsequent applications, examiners must have recognized that the specification disclosed anticipatory one-month data, because Pacira was allowed to add a clarifying footnote to Table 1A without "new matter" rejections. But the lack of a "new matter" rejection does not indicate the absence of new information: as Mr. Godici admitted, the footnote *did* contain new information. Tr. 855:12-24. The lack of "new matter" rejections reflects Dr. Dai's meticulous prosecution strategy: she added the footnote only to applications without one-month claims, ensuring that it would only be analyzed by the PTO once it was no longer directly relevant to the patentability of any pending claims. FOF ¶¶ 562-574.

Anticipation: Defendants are not relying on inherent anticipation, which generally arises when a printed publication does not expressly disclose a claim element. Rather, Defendants assert that the properties of a prior art batch of EXPAREL® may be inferred based on Pacira's own testing of other batches of EXPAREL® made by the same process and same manufacturing lines. This is not "new law," as it is well understood that a party may rely on non-prior art evidence to infer the properties of a prior art product. D.I. 365 at 27-28 (citing cases). In *Exela Pharma Scis., LLC v. Eton Pharms., Inc.*, 620 F. Supp. 3d 108 (D. Del. 2022),

upon which Pacira relied, the court declined to infer the properties of a prior art batch based on only a single non-prior art certificate of analysis of a third-party product; here, *a third* of Pacira's own tested batches met the claim limitations. The facts of this case necessitate a different outcome from *Exela*.

Obviousness: Pacira stated that no witness testified that the small difference in erucic acid concentration lacked a meaningful impact. Not true. Dr. Schwendeman provided extensive testimony, explaining that the small difference of 11 µg/mL between the claimed range and the prior art has no impact on the shelf life, release rate and pharmacokinetics of EXPAREL®. FOF ¶¶ 172-84.

Non-Enablement: The Supreme Court's 2023 *Amgen* decision does not only apply to antibodies. The Court set forth universal principles, including that "the more a party claims, the broader the monopoly it demands, the more it must enable." *Amgen v. Sanofi*, 598 U.S. 594, 614 (2003). The Federal Circuit has applied *Amgen* to find patents not enabled, outside of antibodies. *See In re Starrett*, No. 2022-2209, 2023 WL 3881360, at *4 (Fed. Cir. June 8, 2023) (computer readable medium). Here, Pacira claimed use of all commercial scale processes (regardless of volume), using steps known in the prior art, to yield an MVL composition with certain erucic acid concentration. Here, as in *Amgen*, the specification provides a "research assignment" to conduct trial-and-error testing to make compositions and then test them to see if they practice the claim. That is a "hunting license," not enablement.

Non-Infringement: In *Par Pharma. Inc. v. Hospira, Inc.*, 835 F. App'x 578 (Fed. Cir. 2020), contrary to Pacira's arguments, the Federal Circuit found infringement where the ANDA had a specification for the commercial product which addressed a claim limitation.[2] *Id*. at 586 ("The ANDA states in a line entry in a table [of specifications] that its product satisfies the ICH Q3D guidelines, meaning that it can market and sell a product with up to 30% of the permitted daily exposure of transition metal impurities."). Jiangsu Hengrui's ANDA at issue here, however, has no specification that addresses the claim limitation for testing of erucic acid concentration at 25 ºC. *Par* does not address whether infringement may be based only on development testing submitted to the FDA. In *Ferring I*, however, no infringement was found where no specification applied to the commercial product, despite testing conducted in development at the claimed conditions. *Ferring BV. v. Watson Labs, Inc.-Fla.*, 764 F.3d 1401, 1409 (Fed. Cir. 2014). Pacira is correct that the development testing in that case was done on a product precursor, not the final commercial product (*id.*)—and that reinforces that the infringement inquiry must focus on the proposed commercial product. Here, there is no specification in the ANDA that calls for any erucic acid concentration after storage at 25 ºC for the proposed commercial product.

[2] The specification is explicitly identified in the briefing in the case. Ex. 1 (Excerpt of Par Pharma's Appellate Brief) at 60.

Dated: May 10, 2024

Respectfully submitted,

/s/ Eric I. Abraham

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